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IN THE

# Supreme Court of the United States

FESTO CORPORATION,

*Petitioner,*

v.

SHOKETSU KINZOKU KOGYO KABUSHIKI CO. LTD.
(a/k/a SMC CORPORATION) & SMC PNEUMATICS, INC.,

*Respondents.*

**On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit**

## BRIEF *AMICUS CURIAE* OF GENENTECH, INC. IN SUPPORT OF RESPONDENTS SEEKING AFFIRMANCE

Jeffrey P. Kushan,
*Counsel of Record*
David L. Fitzgerald
Marinn F. Carlson
POWELL, GOLDSTEIN,
FRAZER & MURPHY LLP
1001 Pennsylvania Ave. NW
Washington, D.C. 20004
Tel: (202) 347-0066

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## BRIEF *AMICUS CURIAE*

Pursuant to Supreme Court Rule 37.3(a), on written consent of all parties filed with the Court concurrently with this submission, Genentech, Inc. ("Genentech") respectfully submits this brief *amicus curiae* in support of Respondents.[1]

## INTERESTS OF THE *AMICUS CURIAE*

Genentech is a biotechnology company based in South San Francisco, California. Its corporate mission is to use human genetic information to develop, manufacture, and market pharmaceuticals that address significant unmet medical needs. Founded in 1976, Genentech was the first "biotechnology" company. It has been a pioneer in recombinant protein medicines throughout its existence. Genentech scientists have been granted over 700 United States patents, and the company continues an active program of filing and prosecuting patent applications to protect its inventions.

Genentech is active in all aspects of the patent system. It licenses its technology both to other commercial entities and to academic researchers, and the company regularly takes licenses on patented technology owned by others. It has been a participant in litigation—often involving patent rights of considerable value—as plaintiff, defendant, and third party.

It is hardly lost on Genentech that the rules announced by the *en banc* Federal Circuit in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. Ltd.*, 234 F.3d 558 (Fed. Cir.

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[1] Pursuant to Rule 37.6, *amicus curiae* states that no person or entity other than Genentech or its counsel has made any monetary contribution to the preparation or submission of this brief. Further, no counsel for Petitioner or Respondents authored this brief in whole or in part.

2000), have had immediate and perceptible effects on several aspects of patent practice. In the short term, the new rules are likely to work to Genentech's advantage in some situations, and to its disadvantage in others. But Genentech believes that patent applicants and their attorneys are fully capable of adapting their patent application and prosecution practices to comport with those rules, so as to continue to enjoy the benefits of strong and effective patent protection. It similarly believes that the U.S. Patent and Trademark Office ("PTO") and the courts have the resources to operate effectively in a post-*Festo* environment.

In Genentech's view, the approach to prosecution history estoppel taken in *Festo* is the right one. The decision of the Court of Appeals corrects an imbalance under prior practice between the rights and responsibilities of patentees on the one hand, and the public interest on the other. Moreover, Genentech believes that the complete bar rule, as implemented by *Festo*, will provide substantial benefit over the long term to the biotechnology industry.

## SUMMARY OF THE ARGUMENT

In *Festo*, the *en banc* Federal Circuit established objective, precise, and "workable" standards to govern the effect of prosecution history estoppel in connection with the doctrine of equivalents. Its prior precedent held that a narrowing claim amendment could have widely varying effects on the scope of relief available under the doctrine of equivalents. As a consequence, the literal terms of amended patent claims had become one of the *less* important indicators of the scope of the patentee's enforceable rights.

Clarity and legal certainty promote innovation and investment. *Festo* advances these objectives. It relies on a straightforward indicator, amendments made for reasons substantially related to patentability, that can be reliably evaluated in light of the objective evidence in the prosecution history.



A narrowing amendment, when made by an applicant following a determination by the PTO that the applicant is not entitled to the breadth of protection sought, signals that the applicant has relinquished the right to exclude others from using subject matter outside the scope of the amended claim. The public should be entitled to rely on this surrender, regardless of the particular statutory requirement that formed the basis for the PTO's determination of non-entitlement.

Viewed objectively, the "complete bar" rule provides a number of public policy benefits. Under the *Festo* rule, the notice function of the patent is enhanced by the transparency of the prosecution history. Because patent applicants will amend their claims only when rejections are clearly stated and fully supported, amendments will correlate more closely with patentability. The result will be more thorough and informative prosecution histories. Any disruptions associated with changes to application filing and prosecution practice are likely to be temporary, and they are a reasonable price to pay for the benefits of a better rule.

The Court of Appeals did not purport to eliminate the doctrine of equivalents, and the new rule will not do so in practice. *Festo* simply refines the analysis for measuring the effect of actions taken by patent applicants.

The biotechnology industry will thrive under *Festo*. Federal Circuit precedent and PTO practice allow biotechnology patent applicants to claim their inventions broadly, *provided* that they fully describe and enable the public to practice the invention. This incentive reinforces a sound business strategy: reliance on *literal* claim coverage to protect important inventions, rather than a mere possibility that equitable relief will be available under the doctrine of equivalents. The predictability gained from the new rule will lead to more informed business decisions and will stimulate investment in the industry.

## ARGUMENT

### I. *Festo* provides a balanced, workable, and fair standard for interpreting acts that give rise to prosecution history estoppel.

Prosecution history estoppel serves an important role in balancing the competing public policy interests that motivate the statutory claiming requirement. As this Court has recognized, if the patent system is to promote innovation, a patent must both fairly protect the rights of the inventor and provide reasonable notice to the public of the scope of the property right granted. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 33 (1997) ("claims do indeed serve both a definitional and a notice function"). Neither interest can or should eclipse the other.

Genentech thus does not side with those who urge that the notice function of the claims is paramount. However, based on its experience in procuring, enforcing, licensing, and litigating patents in the biotechnology industry, Genentech does believe that the rules in effect prior to *Festo* have skewed the patent application and prosecution process toward greater uncertainty about the boundaries of patent claims. A rebalancing is in order, and the Federal Circuit's decision accomplishes it.

#### A. *Festo* does not eliminate the doctrine of equivalents, but simply refines its application.

Petitioner and its supporting *amici* portray the majority opinion of the Federal Circuit as effectively extinguishing the doctrine of equivalents. This mischaracterizes the opinion and overstates the impact it will have on the enforceability of patent claims.

The impact of *Festo* is reasonable and precise: its rule concerns *narrowing* amendments made to specific *claim*



*elements* during prosecution for purposes *substantially related to patentability*. Patent owners who have not narrowed claim elements due to patentability deficiencies, or who provide a written record that makes it clear that the narrowing amendment was not made for a reason substantially related to patentability, will enjoy the same access to the doctrine of equivalents as they did prior to *Festo*.

*Festo* only operates when patent owners amend their claims to relinquish subject matter. Under the new rule, that subject matter, relative to the amended claim element, cannot be "recovered" through the doctrine of equivalents. Under pre-*Festo* practice, the relinquishing act *could* but would not necessarily preclude relief. *Festo* creates certainty for both the patentee and the public about the effect of an act of relinquishment.

Notwithstanding the extreme reactions of Petitioner and its *amici*, the Federal Circuit has not abolished the doctrine of equivalents. Rather, it has restated the legal test for the doctrine's availability in situations where the patent owner has disclaimed subject matter. If the condition is satisfied (*i.e.*, there has been no narrowing amendment of a claim element made for reasons related to patentability), then the doctrine of equivalents is fully available. The test relies on evidence that is readily ascertainable from inspection of the administrative record of the patent examination. The doctrine of equivalents remains alive and well after *Festo* and will provide a remedy for patent owners—other than those who would attempt to reclaim that which they expressly disclaimed during the patent's examination.

### B. The *Festo* rule is a fair and workable test for assessing whether a patent applicant has relinquished rights.

The merits of the *Festo* rule should be assessed objectively, and not simply through the lens of its impact on previously granted patents. Certainly, there may be situations where a patent owner will be prejudiced by the application of the *Festo* rule to a record of examination created before the new rule. But the putatively adverse effects of these rules as described by the Petitioner and its *amici* are limited to patents granted before *Festo*. Those citing these patents to challenge the soundness of the *Festo* rule seem to be assuming that patent applicants will not make any extra effort after *Festo* to produce better-documented examination records. Measured prospectively, rather than against these examples, the *Festo* rule is sound, fair, and workable.

As the Federal Circuit majority candidly observed, their holding was designed to address the all-too-frequent reliance on the doctrine of equivalents by an unreasonably large proportion of patent infringement litigants. *See Festo*, 234 F.3d at 578 ("A complete bar reins in the doctrine of equivalents . . ."). The court was justifiably concerned by the inability of members of the public to know—short of the conclusion of litigation involving the patent—whether they could rightfully use subject matter outside the literal scope of the claims.

Under the pre-*Festo* "flexible bar" rule, prosecution history estoppel might limit the scope of equivalents "within a spectrum ranging from great to small to zero." *Hughes Aircraft Co. v. United States*, 717 F.2d 1351, 1363 (Fed. Cir. 1983). Thus, under pre-*Festo* practice, the literal terms of amended claims perversely became one of the *less* important indicators of the scope of enforceable rights retained by the patentee. It was this inability of the public to determine the



scope of rights granted by the patent based on the public record of the patent examination that was the object of the court's holding.

The new rule the Federal Circuit announced does not undermine the doctrine of equivalents or the process used to evaluate equivalents. Instead, it refines the legal test for determining whether relief through the doctrine of equivalents should be available. Specifically, the court discarded a subjective and open-ended standard for determining whether the patent owner's own acts should preclude relief, in favor of an *objective* standard based on publicly accessible evidence in the prosecution record of a patent. The new test certainly is more limiting than the previous standard, especially for those seeking to rely on *post hoc* rationales for the patent owner's actions, but this does not make the test unworkable or unsound.

The inherent uncertainty of the pre-*Festo* "flexible bar" rule has proven to be a windfall for patent owners going far beyond the remedial purposes of the doctrine of equivalents. This uncertainty enabled patent owners to exploit the public's reluctance to risk liability for use of technology related in varying degrees to the patented invention. In effect, the flexible bar rule permitted patent owners to control access to technology within the public domain in addition to the technology specifically claimed in the patent. The patent statute does not and should not grant such barriers to fair competition as part of the reward for an invention.

In contrast, the complete bar rule confines relief under the doctrine of equivalents to a more predictable set of circumstances—namely, those where patentees do not take actions during prosecution of the patents to expressly foreclose their rights to protect insubstantial variations of the invention. As applied in *Festo*, the complete bar provides simply that a doctrine of equivalents analysis is not appropriate where the objective evidence of the prosecution

history indicates that the patent applicant surrendered the subject matter in question. Such a surrender—a narrowing amendment—is almost always the result of an event, such as a rejection by the PTO examiner, that places the patent applicant on direct notice that subject matter embraced by the original claim is unpatentable.

Applying the *Festo* rule to an adequately documented record of examination will reliably yield a fair and equitable result. Evidence in the administrative record of the patent demonstrating that subject matter has been relinquished will control the determination of estoppel against the patent owner with respect to the relinquished subject matter. When an applicant narrows a claim, the applicant is fully aware of the subject matter retained in the claim and that being relinquished. Most patent applicants and their counsel are neither naïve nor incapable of drafting and amending claims that yield the greatest possible breadth of literal coverage. Patent applicants also have alternatives to relinquishing subject matter, including appeal, continuing examination of the application, or even amendment by filing a broadening reissue application within two years of the date of the patent grant, 35 U.S.C. § 251. A patent with broader claims granted on the basis of a continuing application in this scenario will not face the *Festo*-based limitations of the first patent. Given these considerations, the public should be entitled to rely on a clear public record of surrender of subject matter.

### C. The public is entitled to rely on the record of examination to determine the enforceable rights granted to a patent owner.

The prosecution history of a patent should have a primary role in determining the scope of rights granted—and not granted—to the patent owner. It is a defined body of objective evidence, readily available to the public, that documents the administrative examination of the application



by the PTO. Each patent applicant has an ample opportunity to participate in shaping this record before the patent is granted. .

The prosecution history is integral to the notice function served by the patent claims. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979-80 (Fed. Cir. 1995), *aff'd* 517 U.S. 370 (1996). In particular, the second paragraph of 35 U.S.C. § 112 provides:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

This section states two separate requirements. First, the applicant must claim "particularly . . . and distinctly," that is, the claims must convey the metes and bounds of the invention with reasonable clarity. Second, the claims must be directed to the subject matter which the applicant "regards as his invention." *See, e.g., Litton Systems, Inc. v. Honeywell, Inc.*, 140 F.3d 1449, 1461 (Fed. Cir. 1998) (holding that an amendment responding to a rejection based on such grounds was made for a substantial reason related to patentability). By amending claims, an applicant represents that "the invention" (*i.e.*, the subject matter in which enforceable property rights are sought) extends only so far as the literal terms of the amended claims.

The written records contained in the file wrapper of a patent provide a sufficient basis for determining what, if anything, the patent applicant relinquished during the examination of the patent. For example, the PTO may conclude that the applicant is not entitled to the breadth of protection sought in the claims. To reject a claim on such grounds, the PTO must cite a deficiency based on one of the statutory requirements for patentability and support its assertion with suitable argument or evidence. *See In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992) (explaining

the role of a *prima facie* case of unpatentability in *ex parte* examination). In response, the applicant may contest and appeal any such rejection. If improperly imposed, the rejection will be withdrawn without the necessity of a claim amendment. Alternatively, the applicant may choose to amend a claim and accept the consequences of that action. While the applicant's subjective motivation for the amendment may be to expedite the prosecution of the application, that amendment, *in the absence of any explanation*, is the clearest possible indication that the applicant has surrendered the subject matter outside the scope of the amended claim.

Some argue that a patent applicant should not be penalized for "taking the bargain offered by the Patent Office." *See, e.g.*, Chiron *Amicus* Br. at 26. But an offer by an examiner to allow amended claims is not a "deal" subject to the same rules and expectations as a business negotiation. It is instead an indication that the PTO has affirmatively determined only a subset of the claimed subject matter to be patentable. The patent statute and the PTO's rules of practice give the applicant the absolute right, as well as ample opportunity, to contest the examiner's conclusions. It is the applicant, and only the applicant, who holds the power to authorize a narrowing amendment to the claims.

### D. The *Festo* court properly held that a claim amendment made to overcome any patentability deficiency should give rise to prosecution history estoppel.

The *en banc* Court of Appeals held that "a narrowing amendment made for any reason related to the statutory requirements for a patent will give rise to prosecution history estoppel with respect to the amended claim element." *Festo*, 234 F.3d at 566. Petitioner, in contrast, would draw a distinction between unpatentability based on prior art under 35 U.S.C. § 102 and § 103, on the one hand,



and an insufficiency of disclosure under 35 U.S.C. § 112, on the other. *See* Pet. Br. at 26-27. In its view, the former sections of the statute are the exclusive statutory requirements for patentability. The latter, Petitioner argues, involve mere formalities because they appear in a chapter of the statute entitled "Application for Patent." *See id.*

This argument lacks merit. Some of the requirements of 35 U.S.C. § 112 are concededly administrative, such as the restrictions on multiple claim dependence set forth at the fifth paragraph of that section. Others, however, serve important and substantive functions in our patent system, particularly in the field of biotechnology.

The enablement requirement of the first paragraph of 35 U.S.C. § 112, for example, ensures that the applicant is granted claims that correspond to what the inventor has disclosed in sufficient detail to enable a person skilled in the art to make and use the invention without undue experimentation. *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988). Similarly, the written description requirement, a distinct provision of the first paragraph of 35 U.S.C. § 112, serves the evidentiary function of ensuring that the applicant "was in possession of" the claimed subject matter as of the filing date of the application. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991); *see also Regents of the Univ. of Calif. v Eli Lilly and Co.*, 119 F.3d 1559 (Fed. Cir. 1997). The PTO certainly treats both requirements as substantive requirements for patentability, and not as simple application formalities.[2] *See* U.S. Patent &

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[2] Many amendments, particularly under the second, fourth, fifth, and sixth paragraphs of § 112, are made for "substantial reasons related to patentability" but are not "narrowing." Consequently, such amendments will not invoke the complete bar announced in *Festo*. *See, e.g., TurboCare Div. of Demag Delaval Turbomachinery Corp. v. General Elec. Co.*, 264 F.3d 1111, 1125-26 (Fed. Cir. 2001) (amendment "redefin[ing]" claim

Trademark Office, MANUAL OF PATENT EXAMINING PROCEDURE §§ 2163-64 (8th ed. 2001) (hereinafter M.P.E.P.). The PTO similarly uses the utility requirement of 35 U.S.C. § 101 as the basis for substantive rejections of claims. *See* M.P.E.P. § 2107.

Petitioner's attempt to distinguish 35 U.S.C. § 112 deficiencies from those arising under 35 U.S.C. § 102 or § 103 is feeble at best. A determination by an examiner that a claim is not enabled by the disclosure, or cannot be supported by the written description, followed by an amendment to conform the claim to a scope that does not have the deficiencies identified by the examiner, creates an entirely justifiable presumption that the applicant *was not entitled to rights beyond the scope of the amended claims.* Which particular statutory patentability requirement is lacking is irrelevant. To find otherwise would mean that a patent claim found to be unjustified due to an inadequate disclosure at the time of examination could somehow become justified when the patent is enforced.

Moreover, the enablement and written description requirements enforce the fundamental *quid pro quo* of the patent system that a patent should be granted in exchange for the full disclosure to the public of a new and useful invention. A deficiency with respect to either criterion is an entirely justifiable basis for denying a grant of patent or for invalidating an issued patent claim.

It is also notable that 35 U.S.C. § 101, titled "Inventions patentable," states that a patent may be obtained only "subject to the conditions and requirements of this title." This language does not exempt the provisions of 35 U.S.C. § 112 or any other section from the requirements for

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language in response to a rejection under 35 U.S.C. § 112, second paragraph, did not change scope of the claim and thus did not give rise to prosecution history estoppel).



"patentability." Petitioner would have this Court draw a distinction that the statute does not.

### E. A complete bar has significant public policy benefits because it provides certainty as to the scope of patent rights.

"[A] major purpose of claims is to notify the public as to what constitutes infringement." Donald S. Chisum, CHISUM ON PATENTS § 18.02[2] (1998). Under a flexible bar rule, however, the claims can be relied upon only to define the limits of the subject matter in which the patentee *might* assert exclusive rights. The competitor who thoroughly evaluates the prosecution history, reviews all of the relevant prior art, and secures one or more detailed opinions of patent counsel will be rewarded with, at best, informed conjecture about the outer limit of what the patent claims encompass. Even if a court were to eventually determine that the patentee is entitled to enforce only a very narrow range of equivalents, the claims will not have provided notice to the public as to what the public reasonably could expect to practice without liability for patent infringement.

The *Festo* rule provides certainty that advances the public interest in several important respects. First, it helps parties avoid a significant amount of unproductive litigation. Second, it substantially reduces the transaction costs for all market participants in evaluating competing patent positions, particularly in a crowded market involving a mature technology. Third, it provides patent owners and their investors with more reliable assessments of their proprietary positions.

The complete bar rule is also a superior method for assessing what the patentee has surrendered during prosecution. The language of the claims provides a far better indication of what a given amendment was meant to achieve than any subjective evaluation of the applicant's

motivation. The public notice function of the patent is supported by the straightforward and transparent nature of the complete bar rule.

### F. Application of the *Festo* rule does not "take" any property rights held by patent owners.

A number of the *amici* supporting reversal argue that the *Festo* decision represents an unprecedented "taking" of property rights. *See, e.g.*, Wisc. Alumni Res. Found. *Amicus* Br. at 20. As with a number of other characterizations of the decision below, this is neither accurate nor justified.

Patents confer private property rights. 35 U.S.C. § 261 ("Subject to the provisions of this title, patents shall have the attributes of personal property."). Certainly the unauthorized and uncompensated use by the federal government of subject matter claimed in a patent would be an unconstitutional taking of property. *Cf. Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1003-04 (1984) (taking of intangible property cognizable under Fifth Amendment). However, the suggestion that the adoption of the complete bar rule abrogates vested property rights is entirely misplaced.

In assessing these characterizations, it is crucial to recall that the relief available through the doctrine of equivalents has never been a "right" of the patent owner. Instead, it is fundamentally an equitable remedy that courts have provided *notwithstanding* the absence of any literal infringement of the patent claims.

The claims define the property right granted by the government in exchange for disclosure of the invention. As the late Judge Rich noted, "[t]he doctrine of equivalents, by definition, involves going *beyond any permissible interpretation* of the claim language; *i.e.*, it involves determining whether the accused product is 'equivalent' to what is described by the claim language." *Wilson Sporting*



*Goods Co. v David Geoffrey & Assoc.*, 904 F.2d 677, 684 (Fed. Cir. 1990) (emphasis added).

A trial court may invoke its equitable discretion to provide relief to a patent owner for the unauthorized use of *unclaimed* subject matter "equivalent" to the patented invention. But *a priori*, the only assurance that the patent owner has, absent a bar raised by prosecution history estoppel, is that the court will undertake a doctrine of equivalents *analysis*. The availability of a theory for equitable relief cannot be equated to a vested property right associated with the patent.

In *Festo*, the Federal Circuit clarified aspects of a proper doctrine of equivalents analysis. The refinement of a rule governing the circumstances under which equitable relief might be proper has nothing to do with the Constitutional prohibition against the taking of property rights without just compensation.

## II. Concerns over adapting practice to the *Festo* rule can be fairly resolved and should not deter adoption of sound public policy.

Patent law and practice have successfully adapted to changes far more drastic than the changes predicted to result from *Festo*. Indeed, change and adaptation are neither surprising nor unfamiliar to participants in the patent system.

In the last decade alone, the practice of patent law has experienced enormous changes. In 1994, Congress enacted the Uruguay Round Agreements Act, Pub. L. No. 103-465, which *inter alia* changed the way patent term is measured and gave applicants the ability to prove prior invention based on acts in foreign countries. Both provisions led to dire predictions of negative effects when they were proposed, *see generally* Dana Rohrbacher & Paul Crilly, *The Case for a Strong Patent System*, 8 HARV. J. L. & TECH. 263 (1995), but those effects have not materialized. In

1999, Congress adopted the American Inventors' Protection Act, Pub. L. No. 106-113, which, among other things, instituted pre-grant publication of patent applications, new patent term adjustment standards, and significant changes to the PTO's organizational structure. Even greater change lies in the foreseeable future as the United States, led by the PTO, engages in multilateral negotiations in an effort directed toward harmonization of patentability standards on a global basis.

All of these changes have prompted the reevaluation of business strategies by patent applicants and patent owners. They have required patent attorneys to master complicated new bodies of law and procedure. The PTO has promulgated regulations to implement the new laws and has had to manage significantly different workloads arising from changed practice. In spite of disruptions to settled practice caused by significant changes in the law, the patent system has evolved and adapted, and has continued to effectively promote innovation and serve the public interest.

This case involves the judicial treatment of a judicial doctrine rather than a new provision of statutory law. The courts, and particularly the Federal Circuit, are ideally equipped to refine the legal tests—including with respect to the new issues implicated by the *Festo* rule—governing access to the doctrine of equivalents "in the orderly course of case-by-case determinations," *Warner-Jenkinson*, 520 U.S. at 40. As they do, the disruption associated with the new rule will inevitably abate as the new rule becomes the norm.[3]

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[3] Several courts to date have applied *Festo*, arriving at straightforward conclusions, *see, e.g., Control Resources, Inc. v. Delta Electronics, Inc.*, 133 F. Supp. 2d 121, 137 (D. Mass. 2001), even where the Federal Circuit's *Festo* opinion did not address every question required to resolve the issues at hand, *see, e.g., ACLARA Biosci. Inc. v. Caliper Tech. Corp.*, 125 F. Supp. 2d 391, 398-402 (N.D. Cal. 2000); *TurboCare*, 264 F.3d at 1125-26.



### A. Courts will develop rules to govern the interpretation of "intrinsic" evidence regarding the motivations for claim amendments.

As this Court held in *Warner-Jenkinson*, 520 U.S. at 33, there is a rebuttable presumption that an unexplained amendment was made for reasons related to patentability. The Federal Circuit held that a patentee may use only the evidence in the prosecution history itself to explain the basis for an amendment. *See Festo*, 234 F.3d at 586. Key to the latter holding is that patentees should not be able to manufacture *post hoc* rationales to escape the effects of estoppel of their own creation.

The prosecution history of a patent is a defined body of publicly available, objective evidence. It is compiled with the full participation of the patent applicant. Given this combination of characteristics, it is appropriate to rely on the prosecution history as the exclusive source of evidence for evaluating the actions taken by the applicant before the PTO.

This is not to say, however, that all of the relevant evidence relating to the examination of a given application is to be found in the "file wrapper" of the patent (*i.e.*, the collection of papers associated with examination of the patent). The actions documented in the file wrapper occurred within the context of examination policies and the law in effect at the time of the examination of the application. Prevailing law and practice are thus an inherent part of every prosecution history and are available to give context and meaning to the records of the PTO. Genentech believes that it is reasonable, as well as consistent with the Federal Circuit's holding in *Festo*, to take account of suitable objective evidence, such as the edition(s) of the

PTO's *Manual of Patent Examining Procedure* in effect during the pendency of the application, *Federal Register* notices explaining PTO examination standards, and the like, when evaluating the examination record.

### B. Courts will refine when "claim elements" have been "narrowed" and what grounds constitute those "substantially related to patentability."

The *Festo* rule employs certain variables (*e.g.*, "claim element," "narrowing amendment," "substantial reason related to patentability") that govern the determination of whether a patent owner has relinquished subject matter and, as a consequence, should be barred from relief under the doctrine of equivalents. The proper use of each of these variables within the *Festo* framework will be refined through subsequent jurisprudence of the Federal Circuit.

For example, the complete bar rule is to be assessed with respect to a "claim element" that has been "narrowed." What constitutes a "claim element," and whether the claim element has been "narrowed" by an amendment, are issues that future courts will develop rules to govern. Moreover, they will likely develop rules and understandings specific to the differing practices employed in various technological disciplines. Interpretive rules will evolve to provide some flexibility in applying *Festo* to different technological areas.

### C. Continuing applications preserve an applicant's ability to pursue and obtain broad claims.

A patent applicant may file a series of applications based on a single initial application. For each application, the applicant may obtain the priority of the filing date of the first in the series, provided that the claims in the later application are supported in the first. 35 U.S.C. § 120. Multiple patents, each with its own discrete set of claims



and record of examination, can arise from this series of applications.

Continuing application practice gives applicants the option of seeking further examination of broader claims at a later date to resolve issues that turn on additional evidence not available during prosecution of the initial application. For example, where the prior art supports a *prima facie* case of unpatentability under 35 U.S.C. § 103, additional objective evidence, such as that relating to commercial success or a long-felt need in the art, can establish the patentability of the claims. *See Graham v. John Deere Co.*, 383 U.S. 1 (1966). Similar procedural considerations come into play where evidence cited by the PTO calls into question the skilled artisan's ability to practice the full scope of the invention without undue experimentation, as required by 35 U.S.C. § 112, *see In re Wands*, 858 F.2d 731 (Fed. Cir. 1988), or compliance with the utility requirement of 35 U.S.C. § 101, *see* M.P.E.P. § 2107.

Continuation practice benefits the public by promoting the early disclosure of inventions in a first issued patent—without penalizing the patent applicant. Providing the applicant an opportunity to secure broader claims *to which the disclosure entitles him* benefits the public by preserving the stimulus for others to innovate that broad exclusivity provides. Additionally, the more extended examination captured in a second, continuing application provides a thorough, informative prosecution history that supports the interpretation and enforceability of both the narrow claims issued in the first patent and the broader claims in the second.

Existing continuation practice should not be affected by the *Festo* rule on prosecution history estoppel. A contrary rule, holding that the surrender of subject matter by narrowing amendment is final for all purposes and thus effectively eliminating the applicant's option to pursue broader claims in a continuing application, would

undermine the benefits and balance of the *Festo* decision. In this respect, Genentech is confident that courts and the Federal Circuit will develop jurisprudence to refine the *Festo* rule in ways that will preserve the ability of patent applicants to pursue broad claims through continuation practice while obtaining immediate grants of narrower claims in a first application.

### D. *Festo* will promote more informative file histories.

After *Festo*, patent applicants understandably will approach prosecution more carefully than in the past, especially when considering narrowing claim amendments. They will be reluctant to acquiesce to amendments in the face of arguably unfounded rejections, particularly those involving a greater degree of subjectivity. Until the Federal Circuit clarifies the law governing aspects of the complete bar rule, applicants will carefully review the potential consequences of their actions and will behave more conservatively.

The most immediate short-term effect of the *Festo* rule will be that applicants will draft original application claims more carefully and will carefully consider and document any claim amendments. These are all desirable developments that will lead to stronger, more reliable patents that provide clearer notice to the public. Clearer prosecution histories will result because amendments will correlate more closely with valid rejections. More complete records will also better delineate the nature of a surrender of subject matter, whether based on prior art, insufficient description or disclosure, or any other statutory ground of unpatentability.

Likewise, PTO practice is likely to improve in *Festo*'s wake. While several of the *amici* supporting Petitioner have painted gloomy scenarios—arguing that if *Festo* is affirmed the PTO will be overwhelmed by contentious and difficult



prosecutions because prosecuting patent attorneys will submit innumerable claims and refuse to agree to any amendment—they fail to appreciate the beneficial consequences of those same dynamics.

The examination practices of the PTO will surely change in view of the rule announced in *Festo*. What will not change, however, is that applicants will remain motivated to secure patent allowances, and their attorneys will still work to secure literal claim coverage for at least the most important aspects of the inventions.

If some applicants engage in tactics that the PTO finds unreasonably burdensome, it has the administrative experience and the regulatory authority to devise suitable procedures to address and resolve procedural problems. It is also likely that the courts, and in particular the Federal Circuit, will develop clearer rules to neutralize "clever" stratagems designed to escape the effect of *Festo*. The burdens on the PTO are likely to be transitory, much like those that occur when a decision of the Federal Circuit materially alters the application of the statutory criteria for patentability.

The bar's reluctance to accommodate "examiner preference" rejections will, in all likelihood, result in more judicious use of rejections by the PTO and more thorough justifications for them. This trend will be driven by the agency's need to expend its examination resources only on those issues that properly relate to the statutory requirements for patentability. For similar reasons, the PTO is likely to develop practices and procedures that will yield a better examination record and thus higher quality patent grants. The very effects decried by the Petitioner and its chorus will thus in fact benefit patent applicants and the public by promoting better PTO practice.

## III. The Federal Circuit's holding does not establish a disincentive to biotechnology innovation or to the commercialization of patented technology.

Petitioner and many of the *amici* supporting its position express concern that absent an unfettered ability of patentees to resort to the doctrine of equivalents, there will be no incentive to innovate—whether generally, or with respect to biotechnology in particular. Genentech disagrees. The rewards provided by the patent system will remain, and the exclusivity provided by a patent with its attendant market is something that no mere copyist can obtain under the law.

If anything, the decision of the Court of Appeals will restore the proper balance between the disclosure requirements of the patent statute and the grant of exclusivity to the patentee. The new rule will encourage innovation *and* complete disclosure of the invention. The patent applicant who provides both will secure claims of sufficient breadth to effectively deter copyists, and will leave a prosecution history that will better inform members of the public where they may act without fear of infringement liability. Biotechnology will not only survive *Festo*, but will thrive under it.

### A. The biotechnology industry is not built on the doctrine of equivalents.

Genentech fully joins with several *amici* representing biotechnology companies and research organizations in confirming that effective patent protection is critical to innovation and economic vitality in our industry. Genentech parts company with these *amici*, however, when they assert that a complete bar rule, as implemented by the decision below, will drastically undermine the value of existing biotechnology patents and render the procurement of new patents a useless exercise. *See* Chiron *Amicus* Br. at 27; Celltech *Amicus* Br. at 5. Genentech also disagrees with the assertions that biotechnology patents will be limited to



extremely narrow claims, that biotechnology patent applications will be burdened by large numbers of "trivial" examples, or that biotechnology patent holders are especially dependent on the doctrine of equivalents because of uncertainty in the field.

The *Festo* rule will not cripple biotechnology investments. Assertions to the contrary are not consistent with Genentech's twenty-five years' experience in the laboratory, before the PTO, in the courts, and in the business of commercial biotechnology. A patent applicant's fundamental objective in seeking patent protection is to obtain literal claim coverage for commercially important products or methods based on the invention. It is not a rational business strategy for a biotechnology company to prepare a patent application that can literally support only relatively narrow claims and hope that the doctrine of equivalents will preserve a commercially feasible scope of protection in the future.

Other objections also fail to withstand rigorous consideration. Chiron, for example, asserts that biotechnology patent applicants are unable to describe and claim anything more than a single exemplified cDNA sequence. *See* Chiron *Amicus* Br. at 12-14. Numerous U.S. patents granted to Chiron and others flatly contradict this assertion.[4] The courts as well as the PTO have found DNA

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[4] For example, U.S. Patent No. 6,277,590, assigned to Chiron, claims a mammalian "PACE 4" endoproteinase or a functional mutant thereof having substitutions at up to 20% of the residues of a specified reference sequence.

U.S. Patent No. 6,087,144, assigned to Genentech, claims tyrosine kinase polypeptides with reference to coding nucleic acids that hybridize under stringent conditions to (and hence bear a substantial structural similarity to) a reference cDNA.

and protein claims of some breadth to fully comply with the requirements of the patent statute. *See, e.g., Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1212-14 (Fed. Cir. 1991) (broader claims invalid, but claim to DNA "consisting essentially of a DNA sequence encoding human erythropoietin," with no reference to either a specific DNA or amino acid sequence, not invalid for lack of enablement); *In re Wands*, 858 F.2d at 740 (35 U.S.C. § 112 enablement rejection of claims to assays requiring monoclonal antibody proteins defined only in terms of immunological specificity reversed).

Chiron also voices concern that biotechnology patent applications will be burdened with hundreds or thousands of trivial examples, representing the needless expenditure of resources by patent applicants, because the Federal Circuit has allegedly adopted a "rule" that one cannot claim a genus of sequence-based products (DNA or protein molecules) without expressly describing the sequence of each member of the genus. These concerns derive from a naïve misapprehension of the controlling law, and they do not reflect current PTO practice.

The patent law, and in particular the law relating to chemical inventions (which in the view of the Federal Circuit includes biotechnology inventions, *Chugai*, 927 F.2d at 1206 ("[A] gene is a chemical compound, albeit a complex one.")), has never required that an applicant make and test every member of a large genus to obtain comprehensive claims. Rather, to enable a genus, the patent specification must teach the skilled worker how to make and

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U.S. Patent No. 6,235,975, assigned to the University of California, claims "Leafy Cotyledon 1"-encoding nucleic acids with requirements for sequence-specific DNA binding by the polypeptide product, hybridization under stringent conditions to a reference cDNA, and at least 85% identity between the encoded amino acid sequence and a reference amino acid sequence.



use species commensurate in scope with the genus through no more than routine experimentation. *See In re Angstadt*, 537 F.2d 498 (C.C.P.A. 1976); *see also Lilly*, 119 F.3d at 1569 (observing that "enablement of a genus [may be met] by showing the enablement of a representative number of species within the genus," citing *Angstadt*); *In re Wands*, 858 F.2d at 740. Moreover, it is not fatal to a claim if a specified genus includes some inoperative embodiments—for example, compounds that do not exhibit the useful properties possessed by the working examples—so long as the specification teaches how to identify the species that are useful for the disclosed purposes and to distinguish them from those that are not. *See In re Angstadt*, 537 F.2d at 502-03; *In re Wands*, 858 F.2d at 739-40.

This point was broached by the Federal Circuit several years ago in the specific context of claims to DNA encoding a particular amino acid sequence. Owing to the "degeneracy" of the genetic code, very many DNA sequences can encode the same amino acid sequence. In a case that reversed a PTO rejection for obviousness of DNA encoding a protein of previously unknown sequence, the court, in *dicta*, invited the PTO to consider whether a claim directed to any DNA encoding the specified protein was fully enabled. The court noted that the patent disclosure provided only the one naturally occurring DNA sequence encoding the protein. *See In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995). The PTO has apparently declined to make rejections on such grounds, as it continues to routinely issue claims of the form questioned by the court. *See, e.g.*, patents cited *supra* at note 4. This practice is consistent with the perspective of the scientists to whom biotechnology patent disclosures are directed, who understand that "degenerate" DNA sequences are functionally equivalent for the purpose of encoding a given protein.

Neither does the written description requirement of 35 U.S.C. § 112 require the exposition of each sequence within

a claimed genus. The Federal Circuit has held that "a description of a genus of cDNAs may be achieved by means of a *representative number* of cDNAs, defined by nucleotide sequence, falling within the scope of the genus." *Lilly*, 119 F.3d at 1569 (emphasis added). The PTO has adopted this standard as a metric for determining whether a patent application describes the invention in sufficient detail to demonstrate that the applicant was "in possession" of a claimed generic invention at the time the application for patent was filed. *See* M.P.E.P. § 2163. Based on the biotechnology patents issued since the PTO's promulgation of guidelines for written description under 35 U.S.C. § 112, *see* M.P.E.P. § 2163 and patents cited *supra* note 4, it is evident that the PTO accepts that a single example of a DNA sequence encoding a protein of defined sequence is very often sufficiently "representative" of the degenerate DNA sequences encoding the protein to support a claim to the genus.

In summary, neither Federal Circuit law nor the policies or practices of the PTO require an applicant to burden the disclosure with numerous examples of trivial variations of a "sequence" invention in order to secure comprehensive *literal* claim coverage for a reasonable scope of variants.

Chiron also urges this Court to facilitate access to the doctrine of equivalents for biotechnology applicants in view of the "unpredictability" associated with the evaluation of enablement by the PTO. Chiron *Amicus* Br. at 16-17. In a sense, it is true that the result of an enablement inquiry cannot be predicted with certainty. Enablement under 35 U.S.C. § 112 is a question of law which takes into account a number of factual determinations, including those defined by scientific principles. *See In re Wands*, 858 F.2d at 736-37. Enablement is a requirement that cannot be evaluated and applied according to simple formula. But patent practice involves many other fact-based questions of law;



chief among these is obviousness under 35 U.S.C. § 103. *See Graham*, 383 U.S. at 17-18. Though many of these tests require the balancing of substantial amounts of factual evidence and each involves some legal "uncertainty," none has a debilitating effect on patent procurement or enforcement.

In the case of the enablement requirement, the controlling law for biotechnology inventions is by now well-developed, and the PTO has provided detailed guidance to its examiners to ensure its uniform application in biotechnology applications. *See* M.P.E.P. § 2164 *et seq.*[5] Certainly the outcome of an enablement inquiry is more "predictable" than a determination of whether a given product performs substantially the same function in substantially the same way to achieve substantially the same result as a patented counterpart. *See Festo*, 234 F.3d at 591-92 (Plager, J., concurring). In Genentech's view, the application of the enablement requirement is not so fraught with difficulty as to require this Court to intercede on behalf of any particular class of patentees.

### B. The clarity and predictability resulting from the *Festo* rule will promote investment in the biotechnology industry.

Legal certainty encourages wise investments. A mechanism that enables innovators, competitors, and investors to precisely gauge the scope of commercial rights associated with a patent will promote more informed business decisions. Such informed decisions are much more likely to stimulate investment in the biotechnology industry

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[5] *See also* U.S. Patent & Trademark Office, *Training Materials for Examining Patent Applications with Respect to 35 U.S.C. Section 112, First Paragraph—Enablement: Chemical-Biotechnical Applications*, available online at <http://www.uspto.gov/web/offices/pac/dapp/oppd/1pecba.htm>.

and reward its innovators than are decisions based on uncertain predictions linked to the outcome of litigation over speculative claims under the doctrine of equivalents.

Uncertainty is anathema to the economic health of this industry. An equivalence analysis, as applied prior to the decision of the court below, introduced considerable uncertainty into any business decision that relied on the breadth of a patent. *See Festo*, 234 F.3d at 592 (Plager, J., concurring).

None of the formulations used by the courts to determine the "substantial identity" or "insubstantial differences" of claim elements provides certainty for patent owners or the public as to the enforceable scope of patent claims. This is particularly true in biotechnology, where to date only one structurally defined biomolecule has been found to infringe a "sequence" claim through equivalents. *See Amgen, Inc. v. Hoechst Marion Roussel, Inc. and Transkaryotic Therapies, Inc.*, 126 F. Supp. 2d 69 (D. Mass. 2001) (claim to erythropoietin ("EPO") protein held infringed by an EPO product differing only by the absence of one terminal amino acid residue from the 166-amino acid sequence literally required); *see also Festo*, 234 F.3d at 597-598 (Lourie, J., concurring).

Patent applicants, and particularly those developing biotechnology products for clinical medicine, realize that an effective scope of rights is necessary to secure commercially relevant protection for the products they intend to develop. The *Festo* rule will encourage these applicants to support their broad claims in their patent applications and in the prosecution history. Such complete disclosures will fully enable the public to practice all of the claimed subject matter when it passes into the public domain at the conclusion of the patent term.

For genomics inventions, it is particularly easy to determine what the range of proximal equivalents will be



since they will all relate to a narrow universe of known polypeptide structural modifications. It is possible to obtain literal claim coverage for a reasonable scope of variants by providing a complete written description and an enabling disclosure commensurate with the genus claimed, generally including an experimental demonstration of the biological function asserted for the prototypical compound.

## CONCLUSION

For the foregoing reasons, *amicus curiae* Genentech, Inc., respectfully asks this Court to affirm the judgment of the Court of Appeals.

Respectfully submitted,

Jeffrey P. Kushan,
*Counsel of Record*
David L. Fitzgerald
Marinn F. Carlson
POWELL, GOLDSTEIN, FRAZER
& MURPHY LLP
1001 Pennsylvania Ave. NW
Washington, D.C. 20004
Tel: (202) 347-0066

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